

Patient's Safety Information Available On Anesthesia Drug Package Inserts

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Citation

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Abstract

Background: Drug inserts are an important source of information for patients and physicians regarding the safety and proper administration of a drug. However, recent studies have found that inserts are still missing key information regarding a drug's safety and efficacy. The aim of this study was to ascertain whether or not inserts, in King Fahad Medical City (KFMC) Riyadh, anesthesia drugs were deficient with respect to safety and efficacy.

Method: We evaluated the inserts of 50 medications used in routine anesthesia practice in our department against a set of 3 safety criteria Drug interactions information, Hypersensitivity and general precautions.

Results: Inserts were variable in several safety categories for patients, Drug interaction was mentioned in 76%, Hypersensitivity in 76% and general precaution in variable health conditions were in 82% if the drug inserts.

The quality of information was poor in drugs coming from developing countries versus those drugs coming from North America and Europe. 90% of inserts were directed to medical staff, which is going to use it. Only 10% had information directed to patient directly or indirectly through physician warning

Conclusion: The pharmaceutical industry should address this as well as implement the patient safety of dangerous drugs, depending on available animal or human studies.

PROLOGUE

The U.S. Food and Drug Administration (FDA) in 2006 unveiled a major revision to the format of prescription drug information, appearing on the package insert, to give healthcare professionals clear and concise prescribing information. It is hoped to have the most up-to-date information in an easy-to-read form that draws physician and patient attention to the most important drug information before a product is prescribed.

Some studies appeared in recent months investigation studying the general qualities of Drug insert qualities regarding safety precautions and it demonstrated to be inadequate, We were prepared to see the anesthesia drug insert to see the situation in our hospital We were incited to see the situation in our area so was this study.

INTRODUCTION

Pharmaceutical preparations package insert is an essential feature of drug packaging. It is present in most of the

medicines ; [1]. It is considered as the primary source of information for health care providers about drugs [2]. Package's insert is also, a legally required document intended to inform the user of the approved and off label uses of the drug, its dose and any contraindications or adverse effects [1]. Mostly, it is an effective mean to communicate about the risks of drugs [3], and it has an important impact on patients compliance and thus on the ultimate effectiveness of drug use [4]. To achieve its goals, the drug's insert should be clear and comprehensible to convey the intended use of the product, provide an adequate directions for use, warn against potential harmful effects and provide instructions for appropriate length of treatment and when to seek medical advice [5]. Anesthesia used drugs may interact with other anesthetic drugs and any other drugs the patient is taken in the per operative period. The anesthesia drugs are usually used by medical and nursing staff of the hospital and not the patient self administered. So it has to be seen if their insert have enough information to alert the

practitioner about such precautions of use.

On the other hand, drug interactions present a growing concern in the health care settings all over the world. Drug interactions (DI), represent one of the most common forms of adverse drug related events but widely under-recognized source of medical errors [6,7,8,9]. Although, some drug interactions can also be beneficial, they can be harmful either by increasing the toxicity of a drug or by reducing its efficacy [9, 10]. Thus, the consequences of being exposed to an interaction are not trivial. and it has enormous impact on total patient care including the risk of increased hospitalization [11,12]. Preventable drug interactions account for about one third of adverse drug effects but incur about one half of the total adverse effect costs [6, 9]. It is imperative to say that anesthesia practice depends in part on the proper use of such beneficial DI like sedation and analgesia or hypnotic effect of groups of drugs. Still the dangerous DI should be prevented otherwise it may set-in.

Several studies found between 2.2% and 70.3% patients may be affected by potential DI [10]. Other studies have reported that the incidence of DI ranges from 3% to 30% [6]. Again, a number of studies have also estimated the incidence of potential DI in 20-30% of patients with clinically relevant interactions at 4-10% [7, 13,14]. Although, not all drug interactions are clinically significant, it is important to be alert for those that are. But, it is impossible to remember all the known important drug interactions; however, knowledge of the main types of DI will act as a useful alert when prescribing [10]. To treat patients in a competent and safe manner, some awareness of the DI issue and some means of detecting DI are essential [12].

In a recent study on DI [15] in a developing country it was found that no adequate information on DI is available in spite that drug package inserts are likely to be of great importance in the developing countries, where electronic drug alert systems, especially computer-assisted detection of drug interactions are virtually absent. From healthcare professionals to the patients, drug inserts provide most of the information relating to adverse drug reactions, which can be lifesaving [16]. This induced us to conduct an analytical study to explore the extent and nature of information presented in the Anesthesia drug package inserts of most commonly drugs used at King Fahad Medical City (KFMC) in Riyadh KSA. We particularly emphasized on DI, hypersensitivity and precautions of use.

METHODS

SAMPLE SELECTION

The list of basic supply of anesthesia drugs used and most frequent adjunct drugs used routinely during anesthesia was selected for the study. The drug package's insert was read and analyzed to verify the three items related to patient safety namely the DI, Hypersensitivity and precautions of use. Package inserts of the selected products were obtained from The drug packages available with the presented drugs or from general store of Hospital pharmacy for hospital packs, we could not perform randomization of samples. For this we gathered a small convenience sampling of 50 package-inserts from different drug manufacturers during October 15th, 2007 to March 15th 2008. Repeated inserts for the same drugs were excluded from the study.

DATA ANALYSIS

The collected package inserts of different brands were sorted out according to individual drug scientific name and class. Then information were examined and analyzed to obtain necessary information by the Authors [Graduates certified anesthesiologists]. Drug inserts information was enlisted in the pre-formulated table of a personal computer. The information was further cross-checked with the help of the available published and retrievable literatures to determine any substantial omission and consistency of information in the collected package inserts. Descriptive statistical analysis was performed using Microsoft[®] Excel 2007 version Windows XP Professional.

RESULTS

Of the total (n = 50) package inserts, 38 (76%) contained some information on DI while 12 (24%) did not include any. Also 38(76%) contained information on contraindications in case of known hypersensitivity and 41(82%) contained list of precautions concerning concurrent diseases or conditions. Number of package inserts containing precautions information was greater for narcotics, intravenous anesthetic agents, inhalational anesthetic agents and local anesthesia agents injections. A summary of drug package inserts containing information on DI, hypersensitivity and specific precautions appear in (Table 1).

Figure 1

Table 1: Breakdown number of package inserts information [N 50 (100%)]

Type of Information	With information	No information
	N (%)	N (%)
Drug interactions (DI)	38 (76)	12 (24)
Hypersensitivity	38 (76)	12 (24)
Precautions	41(82)	9 (18)

Text book information on DI was not mentioned except in 4 drugs (8%). But none mentioned any rate of occurrence or morbidity of these incidences. Also, there were no statements specifying the DI as dangerous or potential or clinically significant in those package inserts. In most of the cases, no mechanisms were stated to avoid or to reduce the incidences of common DI. A short description of the information on DI extracted from the drug package inserts have been provided in the table 2.

Figure 2

Table 2: Types of precautions for drug actions presented in the package inserts

Characteristics of precautions for drug actions in the package inserts	
Propofol	Children, Severe Cardiac disease
Bupivacaine (spinal)	Anemia, Pyogenic Skin infection, Shock, Hypovolemia hypotension, Coagulation disease
Lignocaine	Severe Cardiac conduction. Adams shock syndrome., CHF, Hereditary suspicion of MH
Isoflurane	Hereditary suspicion of MH, Fever FUO
Sevoflurane	Hereditary suspicion of MH, Fever FUO
Morphine	Acute respiratory depression, asthma attack, acute alcoholism, Paralytic ileus, Pheochromocytoma, heart failure,
	Brain injury. High ICP, Biliary Colic
	Acute respiratory depression, Asthma attack, Acute Alcoholism, Paralytic ileus, Pheochromocytoma, Heart failure,
Moperidine	Head injury high ICP, COPD, Severe Renal impairment, MAO inhibitors, Diabetic Ketoacidosis.

The qualities of this information were evaluated into three classes Excellent, Adequate and Poor. These evaluations do not represent the quality of the drug but the comparative thoroughness of information some drugs insert contained. All excellent information were included in drug inserts coming from USA and Europe. Table 3.

Figure 3

Table 3: Qualities of information and the country of origin of the drugs presented in the package inserts.

Classification	Frequency n (%)	Country of origin of the drugs
		N (%)
Excellent	29 (58)	USA, UK, France, Belgium, Italy, Switzerland, Finland,
		Austria, Germany
		KSA, UAE, UK,
Adequate	14 (28)	Jordan Egypt
		Jordan, Egypt, UK, Italy
Poor	07(14)	Belgium

All information were targeting medical and nursing staff in 90% of insert some 10% has included instruction to the patient either directly or as warning given by the prescribing physician to be informed to the patient.

DISCUSSION

This study demonstrates that the drug package inserts analyzed did include valuable information on DI, hypersensitivity and general precautions in 76% and 82% respectively. The statement- "No significant drug-drug interactions have been observed" was reported, so we considered this as positive sign that DI was considered.

In most countries, drug package inserts should provide all the necessary information in correct and easily understandable form for safe and effective use. The information should be unbiased, should not hide anything [1]. Culminating evidence from developing countries shows that package inserts often contains minimized adverse drug reactions [17]. Drug package inserts also contained either curtailed or no information on important DI or safety precaution. which is an important aspect of overall drug safety [18]. The present study found incomprehensive records of potential DI in the inserts of the most common drug.

CONCLUSION

It seems that the drugs available as imported drugs have variable information in drug inserts. Some do not address fully the patient safety requirements. Improvement should

follow the international tendencies to improve the information on drug inserts to improve safety of the patients.

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